UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/809,650	06/13/1997	GEORGES BAHR	2121-128PCT	7849

2292 7590 05/04/2004

BIRCH STEWART KOLASCH & BIRCH
PO BOX 747
FALLS CHURCH, VA 22040-0747

EXAMINER	
SCHEINER, LAURIE A	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 05/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	08/809,650	BAHR, GEORGES	
	Examiner	Art Unit	
	Laurie A. Scheiner	1648	

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *25,26 and 28-34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *25,26 and 28-34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Claims 25, 26 and 28-34 are pending.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 25, 26 and 28-34 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The recitation of "as a principal ingredient" is considered to be new matter since support cannot be found in the disclosure as originally filed for reasons of record.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 25, 26, 28-30 and 34 are rejected under 35 U.S.C. 102(b) as being anticipated by Schreck et al. for reasons of record.

Claims 25, 26, 28-30 and 34 are rejected under 35 U.S.C. 102(b) as being anticipated by Masihi et al. for reasons of record.

Applicant's arguments filed October 28, 2003 have been fully considered but they are not persuasive.

Regarding the new matter rejection, applicants argue that the proper determination of whether the recitation of the muramyl peptide is administered "as a principal ingredient" is new

matter turns on whether one of skill would have recognized this feature as part of the invention. Applicants contend that the specification teaches that the muramyl peptides are to be administered alone; the administration of the peptide as the main ingredient is therefore clear from the specification.

The examiner disagrees and contends that "administered as a principal ingredient" is not equivalent to "administered either alone, or in combination with antiviral treatments, particularly cytokines" and applicants argument is internally inconsistent. That is, "as a principal ingredient" implies that additional ingredient(s) are employed which is not the same as "administered alone." It appears that applicants intend to support their new matter recitation by the mischaracterization of the word "principal", it appears that this mischaracterization, if accepted, would give breadth to the claim. That is, the claim would necessarily be narrowed by the recitation of "administered alone" (for which the specification does provide support). Again, "principal" is not equivalent to sole or alone; rather, "principal" equates to main, primary, major, etc., however, the specification cannot support a position that the muramyl peptide is the main composition when administered in combination with antiviral treatments such as cytokines, and main does not equate to "alone." Again, "principal" is not the same as "alone" since synonyms of alone include: apart, single, lone, solitary, unaccompanied, exclusive, and only.

With respect to the rejection under 35 U.S.C. 102(b) over Schreck et al. applicants argue that no HIV-1 infected cells were used (Material and Methods). Thus, because there was no exposure to HIV, it was not possible to achieve the invention. Applicants argue that the mere statement that murabutide has been administered to a human does not imply that it has been used with success. Applicants also set forth an inherentcy argument. Applicants contend that

one would not be inhibiting the replication of acquired immunodeficiency retroviruses unless the retrovirus was present.

Applicants' argument is flawed since instant claim 29 recites "for the prevention or treatment of," also, the specification teaches at page 7 that the "molecules of the invention may be used in human clinical medicine either for preventive purposes in at-risk subjects, or for curative purposes in seropositive individuals." Thus, it is clear that prophylaxis prior to viral infection is envisaged and not excluded by the language set forth by the claims. Moreover, claim 25 does not require viral infectivity. Applicants' argument that Schreck et al. fail to demonstrate success of administration of murabutide to a human is disingenuous at best. Applicants are reminded that the instant specification fails to teach the administration of murabutide to a human. Moreover, inhibition of viral replication may be achieved by inhibition of viral infectivity. That is, anticipation is determined by whether or not the method steps of the reference are the same as the positive method steps of the instant claims. Schreck et al. teach the steps as claimed. It appears that applicants confuse conclusions drawn from experimental results with whether or not a method was performed, and said method is not patentable since it is merely a series of old process steps (In re Woodruff (CA FC) 16 USPQ2d 1934 (1990)). Again, applicants are reminded that their claims are not limited to infected individuals since replication can be inhibited by lack of infection. It is noted that a position of inherency with respect to Schreck et al. or Masihi et al. was never asserted by the examiner. Regarding applicants argument that one would not be inhibiting the replication of acquired immunodeficiency retroviruses unless the retrovirus was present contradicts the teachings of the specification since prophylaxis is clearly elucidated, and replication can be completely inhibited if infectivity does not occur. The claims are broad and are in no way limited to specifically inhibiting the replicative

mechanism in infected cells. The references have met the method steps as claimed since the claim (25) requires administering an effective amount of murabutide to an animal. The claim does not require that the animal is infected; thus, the effective amount falls within a range, which is also taught by the references.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laurie Scheiner, whose telephone number is (571) 272-0910. Due to a flexible work schedule, the examiner's hours typically vary each day. However, the examiner can normally be reached Monday thru Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached on (571) 272-0902.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (571) 272-1600.

Correspondence related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official

Gazette, 1096 OG 30 (November 15, 1989). Official communications should be directed toward the following central fax number: (703) 872-9306.

Laurie Scheiner/LAS
April 19, 2004

LAURIE SCHEINER
PRIMARY EXAMINER